

REMARKS

Claims 1, 4-15, 22 and 40 are pending in this application. Claims 1 and 8 have been amended. Claim 40 has been added. Support for the language contained in claim 40 is found in previously presented claim 1. No new matter has been added. In view of the foregoing amendments and following remarks, Applicants believe that the rejections should be withdrawn and that all pending claims 1, 4-15, 22 and 40 are in condition for allowance.

35 U.S.C. § 112 Rejection

Claims 1, 4-15 and 22 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner asserts that while the specification is enabled for bovine lactoferrin and fluconazole for the treatment of *Candida*, it is not enabled for a medicament for treatment and/or prevention of infections and/or inflammation caused by *Candida* species selected from the group of polypeptides listed in claim 1.

Claim 1 has been amended to limit its recitation to a medicament comprising human lactoferrin, bovine lactoferrin, lactoferricin, conalbumin (ovotransferrin), and hydrolysates of lactoferrin. Applicants point out that lactoferricin is a derivative of lactoferrin, and conalbumin and ovotransferrin are related proteins of lactoferrin, all of which together are included in the class known as transferrins. Applicants therefore submit that the specification provides more than adequate enablement for amended claim 1.

Additionally, claim 40 has been added, which recites the peptides previously recited in claim 1. Applicants submit that one skilled in the art would understand that the peptides recited in claim 40 all are derivatives of lactoferrin, and may be obtained by means of hydrolysis of lactoferrin. Thus, claim 40 also is more than adequately enabled by the specification.

35 U.S.C. § 103(a) Rejection

Claims 3, 6, 7, 10, 12-14 and 22 stand rejected under 35 U.S.C. § 103(a) as being obvious over Wakabayashi et al. in view of Steinberg. The Office Action states that claim 3 is rejected, which is a canceled claim.

Applicants assume that the Examiner meant to include claim 1, based on the context of the Examiner's assertions. The Examiner asserts that Wakabayashi et al. teach bovine lactoferrin coupled with fluconazole to inhibit hyphal growth of *Candida albicans* and that Steinberg teaches a polycationic peptide (lactoferrin) and a buffer having a final pH value of 7.0-7.2.

An embodiment of the present invention as now claimed in claim 1 is directed to a medicament for treating or preventing infections and/or inflammation caused by *Candida* species in which the medicament is comprised of a polycationic peptide or protein consisting essentially of lactoferrin, bovine lactoferrin, lactoferricin, conalbumin (ovotransferrin) or hydrolysates of lactoferrin and a buffer in an amount of between about 0.5-100 meq H⁺ in order to maintain the pH of treatable tissue within a pre-selected range of about 5 to 8.5. Claim 1, therefore, is restricted to polycationic peptides or proteins consisting essentially of lactoferrins, related lactoferrin proteins, and derivatives of lactoferrins, in combination with the buffer.

In contrast, Applicants point out that Wakabayashi et al. disclose a beneficial effect of lactoferrin or lactoferricin B solely in combination with triazole antifungal agents on *C. albicans*. Indeed, Wakabayashi et al. teach away from the claimed invention by disclosing that "the peptide alone had almost no effect." Applicants submit that one skilled in the art would understand the teaching of Wakabayashi et al. to mean that the use of lactoferrin or lactoferricin B alone would be ineffective for the treatment of *C. albicans*, and thus one skilled in the art would not be motivated to use only lactoferrin or lactoferricin B to treat *C. albicans* or have any expectation that these compounds alone would be effective to treat *C. albicans*.

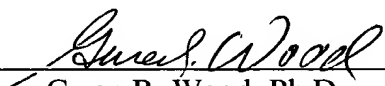
Application No. 09/720,278
Response to Office Action dated May 2, 2006
Paper dated September 5, 2006
Attorney Docket No. 0702-002214

Applicants respectfully submit, therefore, that Wakabayashi et al. do not teach or suggest the administration of lactoferrin compounds alone to treat *C. albicans*, and Steinberg does not cure this deficiency.

In view of the foregoing amendment and remarks, it is respectfully submitted that all pending claims 1, 4-15, 22 and 40 in the present application comply with the requirements of Section 112 and are distinguishable from the cited prior art. Accordingly, reconsideration and withdrawal of the rejections and an early Notice of Allowance are respectfully requested.

Respectfully submitted,

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